K010718

MAR 2 3 2001

Epic Medical Equipment Services
1800 10TH STREET, SUITE 300, PLANO, TEXAS 75074

510(k) Summary

Submitter Information:

Epic Medical Equipment Services, Inc.
1800 E. 10th Street, Suite 300
Plano, TX 75074

Contact:

Krista Oakes
Vice President, Regulatory Affairs and Quality Assurance
Telephone: (972) 801-9854
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Date Prepared:

March 5, 2001

Product Name:

Common Name: SpO2 Ear Sensor (accessory to ear oximeter)
Trade Name(s): Flexi-Site SpO2 Ear Sensor

Predicate Device:

This product is a modification to the Epic Flexi-Site currently marketed under K964055, to extend the available patient monitoring sites to the ear. This product is also equivalent to the Nellcor Dura-Y ear sensor, marketed under K944760.

Description:

The Flexi-Site SpO_2 Sensor is an electro-optical sensor that functions without skin penetration, electrical contact, or heat transfer. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The optical components are housed in a durable silicone casing. The sensor cable is terminated in a DB-9 style connector.

Intended Use:

The Flexi-Site SpO2 Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring.

Comparison to Predicate Device:

The Flexi-Site SpO_2 Sensor uses the same theory and principle of operation as the predicate device. The design is equivalent to the original Flexi-Site, with the addition of a filter and an ear clip accessory to facilitate use on the ear, and is equivalent in accuracy to the Nellcor Dura-Y ear sensor.

Performance Data & Conclusions:

Performance testing was conducted during clinical hypoxia studies conducted in an independent research lab. The Flexi-Site was compared to arterial blood samples analyzed on a laboratory co-oximeter. Accuracy (A_{rms}) for the Flexi-Site was 3.49% across the range of 70%-100% SaO_2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2001

Ms. Krista Oakes
Epic Medical Equipment Services, Inc.
1800 10th Street, Suite 300
Plano, TX 75074

Re: K010718
Flexi-Site SpO2 Ear Sensor
Regulatory Class: II (two)
Product Code: DPZ
Dated: March 9, 2001
Received: March 12, 2001

Dear Ms. Oakes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

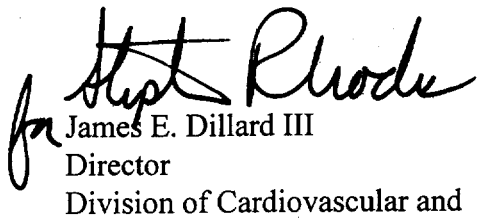
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) # K010718
Device Name: Flexi-Site SpO2 Ear Sensor

Indications for Use:
The Flexi-Site SpO2 Ear Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in patients weighing ≥ 30 kg.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K010718